

Appln No.: 09/937,192

Amendment Dated: December 27, 2004

Reply to Office Action of June 25, 2004

REMARKS/ARGUMENTS

This is in response to the Office Action mailed June 25, 2004 for the above-captioned application. Reconsideration and further examination are respectfully requested.

Applicants request a three month extension of time for response and enclose a Credit Card form for the payment of the fee. The Commissioner is authorized to charge any additional fees or credit any overpayment to Deposit Account No. 15-0610.

The Examiner has reopened prosecution following an Appeals Conference, and now presents two rejections under 35 USC § 112, first paragraph. The first of these rejections is for lack of written description, the second for lack of enablement. Applicants respectfully traverse both of these rejection.

With respect to the written description rejection, the Examiner first asserts that the

independent claims require "a chemical compound comprising first and second hsp-binding moieties which bind to the pocket of hsp90 to which ansamycin antibiotics bind, said binding moieties being connected to one another by a linker." The claims do not require that the compound possess any particular conserved structure, or other distinguishing feature, such as a specific biological activity.

Applicants respectfully submit that this statement made in support of this rejection is in error of several reasons. First, the excerpt from the claims is incomplete. Claims 3, 12 and 13 all state that "the first and second hsp-binding moieties are each an ansamycin antibiotic." The ansamycin antibiotic is a conserved structure. Further, to clarify the biological activity of the compound, claims 3, 12 and 13 have been amended to specify that the first and second binding moieties "retain the ability in the chemical compound to bind to the pocket of hsp90."

The Examiner's argument in support of a lack of written description is not based on the scope of the claim as previously or currently pending. The list of things that can be chemical compounds that spans Pages 2 and 3 of the office action has no connection to the claim as drafted.

The Examiner asserts that the specification does not provide a disclosure of the structure that must be conserved, or the structure/function correlation. Applicants disagree. As a first matter, it must be noted that discussion of conserved structure really relate to protein sequences, not to structure that include two connected ansamycin antibiotics. Further, on Page 5 of the specification, it is taught that the 17-carbon in geldanamycin is the only carbon not buried in the

Appln No.: 09/937,192

Amendment Dated: December 27, 2004

Reply to Office Action of June 25, 2004

binding pocket, and thus a suitable point of linker attachment. While the numbering of the position for compositions containing other ansamycin antibiotics may be different, the desired result, i.e. retaining the ability to bind to the specified binding pocket of hsp90, is the same.

The next statement relating to the present application is found amidst the form paragraphs on page 5 of the Office Action, where the Examiner states that "Applicants have made no assertion that there is any correlation between the biological function of the compound being claimed and its structure." The basis for this statement is not understood. The entire specification makes it clear that the structure of the compound has ansamycin antibiotics that retain their binding function.

On the top of Page 6, the examiner states that "this case was filed before Applicants had a clear idea of the structures of their desired compounds, how to make their compounds or how to use them." The basis for this statement is not explained. Applicants disclose various compounds, including methods of synthesis and a stated use.

These are the only comments besides an ultimate conclusion of lack of written description requirement that appear to relate to this application, as opposed to some other application that was the subject of the Court decision. As such, it is Applicants' position that the Examiner has failed to meet the burden of "presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. MPEP § 2163 (II)(a). Based on the statement of the scope of the claims in the Official Action, he has failed to correctly determine what the claims as a whole covers. Further, he has not alleged any inadequacy in the number of disclosed species within the claimed genus, although he also has not acknowledged the number of species that are disclosed. Accordingly, Applicants submit that the Examiner has failed to put forward "evidence or reasons" supporting the rejection, and that it therefore should be withdrawn. Should the Examiner wish to maintain the rejection, then Applicants submit that it is the Examiner's obligation to show how the facts of the multitude of cases cited relate to this application.

The Examiner also rejected claims 3, 4, 6 and 9-34 under 35 USC for lack of enablement, stating that the claims are only enabled for the a compound in which both chemical moieties are geldanamycin, the linker is a 4 carbon linker bonded to the 17-carbon of geldanamycin, and to the use of this compound in the treatment of breast cancer. Again, the characterization of the scope of the claims is incomplete.

The Examiner on page 9 of the official action that "the breadth of the claims includes billions of compounds with radically diverse structures which bind to the pocket of hsp90." Applicants challenge the Examiner to support this statement with compounds that don't venture

Appln No.: 09/937,192

Amendment Dated: December 27, 2004

Reply to Office Action of June 25, 2004

into the absurd. The parts of the claims that the Examiner has omitted from his characterization specify that the molecule contains two ansamycin antibiotic moieties. The Examiner has not established that this is class containing a multiplicity of compounds of diverse structure as the Examiner argues.

The Examiner's limiting the scope of enablement to compounds with 4 carbon linkers is also inconsistent with the specification. The specification discloses results from compounds with two geldanamycin moieties linked by 4, 7, 9, and 12 carbon linkers. In each case, activity and selectivity is observed, although the 4-C linker was most active and most selective. (see Table 1). Further, the specification discloses other forms for linkers, including the aryl linker and the N-methyl-amino linker shown in Fig. 1.

As to the statement that the claims are only enabled for breast cancer, the Examiner has not provided a single argument addressed to this point. He has cited cases, including the *Angen* case which relates to written description not enablement (Page 10), and references a case that refers to "probable utility" but has not applied any of this to the present matter. Thus, he has failed to meet the burden placed on the Examiner in making an enablement rejection of providing acceptable reasoning inconsistent with enablement. *In re Strahilevitz*, 212 U.S.P.Q. 561, 563 (C.C.P.A. 1982). Further, to the extent the Examiner is asserting that the claimed invention may not work in cancers other than breast cancer, the Examiner is required to support an enablement rejection where the operability of materials beyond the scope of specific examples is challenged by the Examiner. *In re Bowen*, 492 F. 2d 859, 181 U.S.P.Q. 48 (C.C.P.A. 1974). This has not been done. Thus, the Examiner has failed to present an enablement rejection to which Applicants can reasonably respond. The rejection should therefore be withdrawn.

It is also noted that the Examiner has, despite repeated requests by Applicants, once again not even mentioned the declarations and the exhibits A-O which are of record in this case. The Examiner cannot pick and choose among the evidence of record, but must consider all of the evidence. Accordingly, should the rejection of the present claims be maintained, Applicants DEMAND a statement by the Examiner that these materials have been considered and an explanation as to why the Examiner finds them insufficient.

Finally, the Examiner has provisionally rejected the claims of this application for § 101-type double patenting in view US 09/960,665. Applicants note this rejection. However, with the present amendment the claims are no longer identical. Accordingly, this rejection is believed to be moot.

Appln No.: 09/937,192

Amendment Dated: December 27, 2004

Reply to Office Action of June 25, 2004

For these reasons, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully submitted,

Marina Larson

Marina T. Larson, Ph.D

Attorney/Agent for Applicant(s)

Reg. No. 32038

(970) 468 6600

Page 8 of 8